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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,933	04/15/2004	James R. Braig	OPTIS.100A	7558

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

AKANBI, ISIAKA O

ART UNIT	PAPER NUMBER
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2886

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/21/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/21/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary

Application No.

10/824,933

Applicant(s)

BRAIG ET AL.

Examiner

Isiaka O. Akanbi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Amendment

The amendment file 14 February 2007 has been entered into this application. Claims 41-45 have been added.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 41 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Sterling et al. (2003/0090649 A1).

As regard to claims 1, 41 and 45, Sterling discloses a reagentless sample element comprising of the following:

first and second (360/350) substantially parallel faces, the parallel faces at least partially defining a sample chamber configured to hold a volume of fluid, the sample chamber being reagentless, an optical path extending through the parallel faces and the sample chamber, such that electromagnetic radiation can propagate through the sample chamber, an identifying compound disposed in the optical path, the identifying compound (i.e. blood components) having at least one indexed optical absorbance feature, such that spectral analysis of electromagnetic radiation propagated through the identifying compound yields the indexed optical absorbance feature, the identifying compound being disposed within or on at least one of the parallel faces and separated from the sample chamber such that the identifying compound does not intermingle with the sample fluid (figs. 15-16A)(see abstract)(pars. 0158-0172).

As to claim 2, according to claim 1, Sterling discloses wherein the first and second substantially parallel faces are at least partially transmissive to electromagnetic radiation (par. 0162).

As to claims 3 and 4, Sterling discloses wherein the parallel faces are at least partially transmissive to infrared electromagnetic radiation and wherein the indexed optical absorbance feature is adjacent to or overlapping an absorbance feature of an analyte detectable by the analyte detection system (pars. 0064, 0066)(figs. 13-18A).

As to claims 5 and 6, Sterling discloses wherein the analyte detectable by the analyte detection system is glucose and the indexed optical absorbance feature is an absorbance maximum or an absorbance minimum (i.e. appropriate level)(par. 0005).

As to claim 7, Sterling discloses wherein the identifying compound is a hydrocarbon (par. 0065).

As to claim 8, Sterling discloses wherein the identifying compound is a coating on at least a portion of the sample element (pars. 0073, 0076-77 and 0092).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-12 and 31-37, 40 and 42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Jina et al. (5,526,120).

As regard to claims 9, 31-33, 40 and 42-44, Jina discloses a method for determining an analyte concentration in a material sample disposed in a sample element comprising of the following:

an optical path for determining analyte concentration (fig. 2)(col. 1, line 7-11),
and an identification key (56/60) in the optical path, the identification key comprising a physical property of the sample element (figs. 1, 4 and 5)(col. 6, line 40-43),
receiving (14) the sample element (10) in an analyte detection system, after receiving, qualifying the sample element by determining whether the sample element is of a type which is suitable for use with the analyte detection system (12), if the sample element is of a type which is suitable for use with the analyte detection system, analyzing an optical property of the

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material sample (and if the sample element is not of a type which is suitable for use with the analyte detection system, refusing to analyze an optical property of the material sample (figs. 1, 4-12)(col. 6, line 40-43)(col. 12, line 12-col. 14, line 1-5).

As to claim 10, according to claim 9, Jina discloses wherein the physical property is an optical absorption of a window in the optical path (figs. 1 and 5-12).

As to claims 11 and 12, Jina discloses wherein the physical property is a thickness of a window in the optical path and wherein the physical property is a thickness of sample chamber in the optical path (figs. 7-12).

As to claim 34, Jina discloses wherein qualifying the sample element comprising measuring an optical absorbance spectrum of the sample element and analyzing the measured optical absorbance spectrum for a qualifying absorbance feature (col. 1, line 6-11).

As to claim 35, Jina discloses wherein the qualifying absorbance feature is an absorbance maximum or an absorbance minimum (col. 3, 38-col. 4, line 1-2).

As to claim 36, Jina discloses wherein qualifying the sample element comprises reading at least one datum from an identification medium (col. 4, line 48-54).

As to claim 37, Jina discloses wherein qualifying the sample element further comprising checking whether the datum corresponds to a datum stored in the analyte detection system (col. 3, line 39-47).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jina et al. (5,526,120) in view of Douglas et al. (5,962,215).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jina in view of Douglas, as applied to claim 9 above. The reference of Jina teaches of the features of claim 13, comprising physical property (figs. 1 and 5-12), however the reference of Jina is silent regarding the wherein the physical property is a background optical absorbance spectrum of the

optical path. The reference of Douglas teaches of calibration (col. 6, line 45-53)(col. 16, line 7-15). It would have been obvious to one having ordinary skill in the art at the time of invention to include physical property that is a background optical absorbance spectrum of the optical path for the purpose of providing a more accurate measurement.

As to claims 38 and 39, Jina discloses everything claimed, as applied to claim 36 above, except for the reference of Jina is silent regarding wherein the identification medium comprises a bar code and wherein the identification medium comprises a magnetic strip. The reference of Douglas teaches of a bar code and magnetic strip (col. 24, 43-48). It would have been obvious to one having ordinary skill in the art at the time of invention to provide an identification medium comprising a bar code and a magnetic strip for the purpose of providing a more accurate calibration information and detection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-18 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Douglas et al. (5,962,215).

As regard to claim 14, Douglas discloses a sample element for use with an analyte detection system comprising of the following:

a sample chamber (49) and an identification key (61/101) that is located within or on the sample element and that is configured to indicate to the analyte detection system a qualification state of the sample element (figs. 1-3)(col. 16, line 2-15)(col. 17, line 52-55)(col. 19, line 10-28).

As to claim 15, according to claim 14, Douglas discloses wherein the identification key is configured to indicate a qualification state in which the sample element is configured for use with the analyte detection system (col. 16, line 7-15).

As to claims 16 and 17, Douglas discloses wherein the identification key (61/101) comprising a compound (Barcode on strip) having an optical absorbance spectrum with a qualifying optical absorbance feature and wherein the qualifying optical absorbance feature is

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adjacent to or overlapping an absorbance feature of an analyte detectable by the analyte detection system (72)(figs. 1-3)(col. 24, line 36-47).

As to claim 18, Douglas discloses wherein the analyte detectable by the analyte detection system is glucose (col. 1, line 13-14).

As to claim 21, Douglas discloses wherein the identification key (61/101) has a structure configured to mechanically engage a complimentary structure in the analyte detection system, such that mechanical engagement of the sample element with the analyte detection system indicates to the analyte detection system a qualification state of the sample element in which the sample element is configured for use with the analyte detection system (fig. 3B)(col. 16, line 6-15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. (5,962,215) in view of Sterling et al. (6,312,888 B1)

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over of Douglas in view of Sterling, as applied to claims 16. The reference of Douglas teaches of the features of claim 19, comprising qualifying optical absorbance feature (61/101), however the reference of Douglas is silent regarding the qualifying optical absorbance feature as having (i.e. an absorbance maximum or an absorbance minimum). The reference of Sterling teaches of optical absorbance feature with (colorant)(i.e. appropriate level)(col. 3, line 17-27) (col. 1, line 25-41). It would have been obvious to one having ordinary skill in the art at the time of invention to provide the qualifying optical absorbance feature that have (i.e. an absorbance maximum or an absorbance minimum) for the purpose of providing a more accurate measurement.

As to claims 20 and 24, Douglas and Sterling disclose everything claimed, as applied to claim 19 above, except for the reference of Douglas is silent regarding wherein the compound comprising a hydrocarbon. The reference of Sterling teaches of hydrocarbon (i.e. a dye or

pigment)(col. 9, line 66-67). It would have been obvious to one having ordinary skill in the art at the time of invention to provide compound that comprises a hydrocarbon (i.e. a dye or pigment) for the purpose of providing a more accurate measurement and detection.

As to claims 25 and 26, Douglas and Sterling disclose everything claimed, as applied to claim 24 above, in addition Douglas discloses wherein the identification medium comprising a bar code and magnetic strip (col. 24, 43-48)

Claims 22, 23 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. (5,962,215) in view of Sterling et al. (6,312,888 B1) and further in view of Jina et al. (5,526,120)

Claims 22, 23 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Douglas in view of Sterling, and further in view of Jina, as applied to claims 14. The reference of Douglas teaches of the features of claim 21, comprising an identification key (61/101)(fig. 3B)(col. 16, line 6-7), however the reference of Douglas and Sterling is silent regarding wherein the identification key structure is a physical shape. The reference of Jina teaches of an identification key (56/60) structure with a physical shape (figs. 1, 4-12)(col. 6, line 40-43)(col. 12, line 12-col. 14. line 1-5). It would have been obvious to one having ordinary skill in the art at the time of invention to provide identification key structure that has a physical shape for the purpose of providing a more accurate calibration and detection

Additional Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The references listed in the attached form PTO-892 teach of other prior art sample element that may anticipate or obviate the claims of the applicant's invention.

Response to Arguments

Applicant's arguments/remarks, see pages 9-12, filed 14 February 2007, with respect to the rejection(s) of claim(s) 1-8 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of claim amendment. As to Applicant's arguments

with respect to rejection of claims 9 and 10 that cited reference Jina as neither described/suggest an identification key configured to indicate a physical property of the sample element and window, the examiner disagrees with the applicant arguments. The reference of Jina shows an identification key that in the optical path (56/60/76/78/82) configured to indicate a physical property of the sample element and window provided for reading the reaction zone (63)(figs. 1, 4-8)(col. 6, line 40-43). Additionally, as to applicant arguments on page 11 that cited reference Douglas neither described/suggest qualification state of the sample element, the examiner disagrees with the applicant arguments. The reference of Douglas shows an identification key (61/101) that is located on the sample element (49)(figs. 1-3) that qualify the state of the sample element. Further, in response to applicant's argument in regard to claim 31 that cited reference, Jina as neither described/suggest qualifying the sample element by determining whether the sample element is of a type, which is suitable for use with the analyte detection system, the examiner disagrees with the applicant arguments. The reference of Jina shows whether the sample element is of a type, which is suitable for use with the analyte detection system (figs. 1, 4-12).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Fax/Telephone Information

Any inquiry concerning this communication or earlier communications from the examiner

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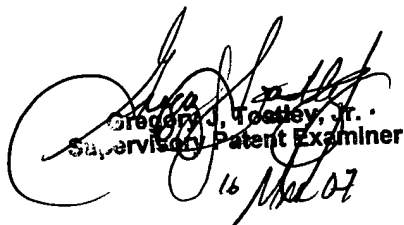
should be directed to Isiaka Akanbi whose telephone number is (571) 272-8658. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Toatley Jr. can be reached on (571) 272-2059. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isiaka Akanbi

March 13, 2007


Gregory J. Toatley, Jr.
Supervisory Patent Examiner
16 Mar 07